NOV 16 2004

K042877
Page 1 of 2

510(k) SUMMARY

Percutaneous Systems, Inc.'s MICROVERTER Ureteral Access Sheath

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Percutaneous Systems, Inc.
1300 Crittenden Lane, #301
Mountain View, CA 94043-1359

Phone: (650) 969-8800 x 204
Facsimile: (650) 969-8801

Contact Person: Thomas Lawson

Date Prepared: September 25, 2004

Common or Usual Name

Urology Introducer Sheath

Classification Name

Accessories, Catheter, G-U

Predicate Device

PSI SLIP Urology Introducer Sheath
Cook Flexor Ureteral Access Sheath
Boston Scientific Navigator Ureteral Access Sheath

Intended Use / Indications for Use

The MICROVERTER Ureteral Access Device is intended to facilitate the introduction of endoscopes and other instruments into the urinary tract. The device is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the

urinary tract, and as a lubricious barrier between the ureteral tissue and the endoscope or instrument.

Technological Characteristics

The MICROVERTER Ureteral Access Sheath consists of a film membrane covering an outer tube, and a pusher tube that provides a lumen for the introduction of endoscopes and instruments. The outer tube is pre-loaded with the film membrane.

Performance Data

Performance data demonstrated no significant difference in the performance of the MICROVERTER Ureteral Access Sheath and the predicate device.

Substantial Equivalence

The MICROVERTER Ureteral Access Sheath has the same intended use, indications for use, and principles of operation and very similar technological characteristics as the predicate devices. Thus, the MICROVERTER Ureteral Access Sheath is substantially equivalent to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2004

Thomas Lawson, Ph.D.
Director, Clinical Affairs
Percutaneous Systems, Inc.
1300 Crittenden Lane, #301
MOUNTAIN VIEW CA 94043-1359

Re: K042877
Trade/Device Name: MICROVERTER Ureteral Access Sheath
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 KNY
Dated: September 25, 2004
Received: October 18, 2004

Dear Dr. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K042877

Device Name: MICROVERTER Ureteral Access Sheath

Indications for Use:

The MICROVERTER Ureteral Access Sheath is intended to facilitate the introduction of endoscopes and other instruments into the urinary tract.

The MICROVERTER Ureteral Access Sheath is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract, and as a lubricious barrier between the ureteral tissue and the endoscope or instrument.

Prescription Use __x___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____
_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042877